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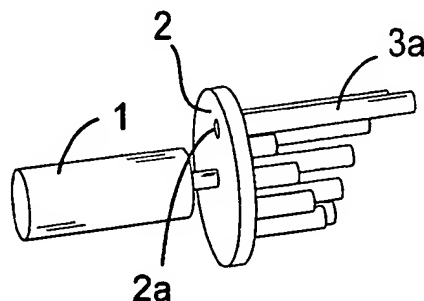
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(54) **Adjustable resistance valve for a cerebrospinal fluid shunt system**

(57) The present invention concerns an adjustable resistance valve for a cerebrospinal fluid shunt system comprising an actuator (1) allowing the selection of the resistance to flow of the valve, selecting means (2) with at least one passage (2a) traversing these selecting means, and a resistance system (3). This resistance system comprises a set of passages defining each a different resistance to flow, the passages being situated

around a circle facing said selecting means (2) such as to guide the flow of the cerebrospinal fluid traversing said passage (2a) of the selecting means (2) through the selected passage of the resistance system (3). Said actuator (1) enables to change the relative position of the selecting means (2) with respect to the resistance system (3) by a rotational movement in order to select the desired resistance of the valve.

Fig.1a



Description

[0001] The present invention relates to an adjustable resistance valve adapted to be used within a shunt system for the treatment of hydrocephalus as well as to a cerebrospinal fluid shunt system itself and, where appropriate, the corresponding method of treatment of hydrocephalus using the adjustable resistance valve respectively the cerebrospinal fluid shunt system.

[0002] In the ventricular system of the brain the so called cerebrospinal fluid (CSF) is formed at a given formation rate. This formation happens regardless of the intracranial pressure exerted on the brain by the cerebrospinal fluid, this latter normally being evacuated at a certain flow rate into the sagittal sinus as the natural CSF resorption site. In case of an obstruction along the natural cerebrospinal fluid pathway, which starts at the level of the ventricles of the brain situated in the middle of the cranium and ends in the sagittal sinus, the outflow of CSF from the ventricular system is reduced or completely interrupted leading to a pathological increase in the amount of cerebrospinal fluid located inside the cranium near its formation site. This pathological increase in the amount of intracranially located CSF or hydrocephalus causes an increase of the intracranial pressure, as the formation of CSF is widely independent of its evacuation.

[0003] Hydrocephalus is currently treated by either restoring the physiological CSF pathway by endoscopy, a method which can only be applied under certain conditions and which is limited in its success primarily by a high probability of re-obstruction of the natural pathway, or by derivation of the excess of CSF into a remote resorption site by using artificial means called shunt, thus restoring the normal physiological value of the intracranial pressure.

[0004] Such devices for the treatment of hydrocephalus by derivation of the excess of CSF are well known and make use either of resorption sites outside the cranium, by installing a shunt from the ventricular system of the brain to an adapted resorption site like the peritoneal cavity or the right atrium of the heart, or of the natural resorption site, the sagittal sinus, by trying to restore a pseudo-physiological pathway.

[0005] These devices primarily consist of three parts. A first part often called a proximal catheter is introduced in the ventricles of the brain and allows the draining of CSF from the ventricles. A second part called a distal catheter, which is usually similar in its realisation and functioning to the proximal catheter, is introduced in a distal resorption site like the atrium, the peritoneum or the sagittal sinus and allows drainage of CSF into the site. A third part, the main body of the shunt, is connected between the proximal and distal catheters and comprises means for regulating the drainage of CSF through the shunt, e.g. a valve or the like.

[0006] The method using other body cavities than the natural site as resorption site is the most commonly

used one, the corresponding devices draining the CSF from the ventricles of the brain to the peritoneal cavity or to the right atrium of the heart, which have been found to be the most suitable diversion sites for CSF outside the cranium. For these kind of devices one knows several means regulating the flow of CSF through the shunt which primarily make use of one parameter, the pressure, amongst the several parameters one would consider to be important or convenient for the regulation process.

[0007] These regulating means can be classified in differential pressure valves and variable resistance valves. Differential pressure valves regulate the differential pressure across its ends, i. e. the difference of the pressure captured at the far ends of the catheters, some of these valves also permitting to select one of several possible values of the opening pressure of the valve non-invasively after implantation in order to allow a more flexible handling of the shunt. The main drawbacks of these devices are the so called siphoning effect and the unknown peritoneal pressure changes.

[0008] The first effect is due to hydrostatic pressure changes, e.g. when the patient changes position from the horizontal to the vertical position leading to a sudden increase in the hydrostatic pressure along the shunt. In that case, such a valve will open and drain most of the CSF of the ventricles of the brain until the pressure across the valve itself falls below its opening pressure. This inherits the danger of hyperdrainage leading to subnormal intracranial pressure. The patent US 5192265 describes an example of a shunt trying to overcome these difficulties by proposing a rather complex anti-siphoning device allowing to select transcutaneously the resistance to flow by controlling the surrounding pressure of a channel having flexible walls.

[0009] The second effect is related to the fact that the shunt provides a connection between the ventricles of the brain and the peritoneum, the pressure of which being unknown. Therefore, it is impossible to anticipate the intracranial pressure, even if the opening pressure of the shunt is known, thus making it impossible for the surgeon to select the correct opening pressure a priori.

[0010] Variable resistance valves regulate the flow of CSF through the shunt by varying the resistance of the valve as a function of the distal pressure. These devices are in principle insensitive to the siphoning effect, but inherit the problem of necessitating access to atmospheric pressure. As the device is implanted, it makes it sensitive to subcutaneous pressure which is quite variable, and sensitive to the presence of scar tissues.

[0011] The other method for the treatment of hydrocephalus by artificial derivation of the excess of CSF consists in the installation of a shunt from the ventricular system of the brain to the natural resorption site, the sagittal sinus, the shunt then forming a pseudo-physiological pathway. This method was used less frequently in the past, but is nevertheless the object of current research. The document W09811934 presents an over-

view of several existing devices in this field, it also explains the reasons for using the resistance to flow instead of the pressure as a parameter in a regulating device for a cerebrospinal fluid shunt. These reasons are primarily to avoid hyperdrainage of the ventricles of the brain by limiting the flow through the shunt and to allow to design a device reflecting the properties, especially the resistance to flow, of the natural CSF pathway. This document describes a device for the treatment of hydrocephalus having a fixed resistance to CSF flow which is designed to define a resistance similar to the normal resistance of the natural pathway from the ventricles of the brain to the sagittal sinus. Due to its fixed resistance the device cannot be fine tuned to the individual needs of a patient, i.e. after implementation it doesn't allow the surgeon to fit the resistance of the derivation circuit to match the resistance of the normal CSF resorption pathway of a specific pathway. Also, due to its very limited range in resistance to flow around 10 mm Hg/ml/min, the proposed device is limited to a treatment of hydrocephalus using the sagittal sinus as resorption site.

[0012] The aim of the present invention is to remedy to the inconveniences of the current systems by providing an adjustable resistance valve adapted to be integrated into a shunt system for the treatment of hydrocephalus, the resistance to CSF flow of the valve being adjustable non-invasively after implantation, the range of resistance to CSF flow covering the necessities of all possible resorption sites and the device being of simple construction.

[0013] Therefore, the object of the present invention is an adjustable resistance valve for a cerebrospinal fluid shunt system comprising the characteristics mentioned in claim 1 and/or the dependent claims.

[0014] Another object of the invention is a cerebrospinal fluid shunt system incorporating an adjustable resistance valve having the characteristics mentioned in claim 9 as well as, where appropriate, a method of treatment of hydrocephalus using the adjustable resistance valve respectively the cerebrospinal fluid shunt system as specified in claim 12.

[0015] The annexed figures represent, as an example, several embodiments of a device according to the invention.

[0016] Figures 1a to 1c schematically illustrate the principle of two embodiments of an adjustable resistance valve for a cerebrospinal fluid shunt system according to the present invention.

[0017] Figures 2a to 2b schematically illustrate the principle of another embodiment of an adjustable resistance valve for a cerebrospinal fluid shunt system according to the present invention.

[0018] Figure 3 is a schematic view of an adjustable resistance valve according to the present invention integrated in a cerebrospinal fluid shunt system.

[0019] Figure 4 schematically represents a cerebrospinal fluid shunt system disposed on the cranium.

[0020] The invention will now be described in detail

with reference to the annexed figures which are illustrating by way of example several embodiments of the invention.

[0021] An adjustable resistance valve for a cerebrospinal fluid shunt system according to the present invention comprises, like illustrated in figures 1a to 1c and 2a to 2b, an actuator 1 allowing the selection of the resistance to flow of the valve, and selecting means 2 with at least one passage 2a traversing these selecting means.

A preferential realisation of such selecting means is a disc 2 with at least one passage 2a traversing the disc near its periphery in a direction parallel to its longitudinal axis. Furthermore, an adjustable resistance valve according to the present invention comprises a resistance system 3 comprising a set of passages defining each a different resistance to flow, the passages being situated around a circle facing said selecting means 2 such as to guide the flow of the cerebrospinal fluid traversing said passage 2a of the selecting means 2 through the selected passage of the resistance system 3. In the above mentioned case of a disc 2 as selecting means which will be used in the following explanations of the description for reasons of simplification, the passages of the resistance system 3 would preferentially be parallel to said axis of the disc 2. The disc 2, i. e. in general the selecting means 2, is adapted to be rotated by means of said actuator 1 in order to select the desired resistance of the valve by positioning the disc 2 such as to allow the flow of the cerebrospinal fluid traversing said passage 2a of the disc 2 through the selected passage of the resistance system 3. However, it is the relative position of the selecting means 2 with respect to the resistance system 3 which is important, thus it could as well be the resistance system 3 which is rotated with respect to the selecting means 2 by means of said actuator 1, this case not being explicitly illustrated in the figures. Thus, in general, said actuator 1 enables to change the relative position of the selecting means 2 with respect to the resistance system 3 by a rotational movement in order to select the desired resistance of the valve.

[0022] The actuator 1 comprises a motor connected to the disc 2 or to the resistance system 3 in order to drive the rotational movement of the disc 2 with respect to the resistance system 3, an energy source such as for example an antenna that can be coupled inductively to an external RF source or a battery, and corresponding electronics that will drive the motor, give feedback to the user about the actual relative position of the disc 2 with respect to the resistance system 3 and manage the energy consumption of the actuator.

[0023] The disc 2 comprises one passage 2a and is mounted such as to be able to turn in order to place the passage in the desired position for the selection of the required resistance to flow. Due to the reasons just mentioned, it could also be the resistance system 3 instead of the disc 2 which is mounted such as to be able to be rotated. The size of the passage 2a will be chosen such

as not to limit the resistance of the passage with the smallest resistance to flow of the resistance system 3. As shown in figures 1 and 2, the passage 2a is preferably situated at the periphery of the disc 2 in order to allow a geometrically favourable arrangement of the passages of the resistance system 3. However, it is also possible to equip the disc 2 with several passages situated on the disc 2 in a geometrically adequate manner, e. g. at a different radius from the centre of the disc 2 and in correspondence to the arrangement of the resistance system 3, in order to allow a more efficient use of the available space, the disc 2 still allowing to choose a certain value of resistance to flow. The following description will, for reasons of simplicity, refer to the solution with one passage 2a in the disc 2 as depicted in the figures, without however limiting the scope of the invention.

[0024] The resistance system 3 itself comprises a set of passages corresponding to a set of resistances to flow. These resistances may be realised as shown in a first embodiment in figures 1a and 1b by means of a set 3a of different tubes having each an identical internal diameter but a different length, these tubes being arranged parallel to each other, the openings disposed around a circle corresponding to the rotational movement of the passage of the disc 2. As shown in figure 1c, a second, functionally equivalent embodiment may consist of a body of essentially cylindrical shape 3b comprising a set of passages e.g. drilled into it and being disposed such as to form analogously a set of passages parallel to each other and to the axis of the body as well as to the axis of the disc 2, with the openings of the passages facing the rotational path of the passage of the disc 2. In order to obtain the different lengths of the passages of the body of cylindrical shape 3b, the body 3b comprises on its one end a recess of helicoidal shape, on the surface of which the passages depart.

[0025] The resistance system 3 may also be realised as a set of tubes disposed analogously to the one described in the first embodiment, the tubes however having all the same length, and in this case each a different internal diameter and forming thus a system of a variety of different resistances to cerebrospinal fluid flow. The same effect will be obtained by choosing an embodiment as depicted schematically in figures 2a and 2b. Here, the set of tubes described above is simply replaced by a second disc or cylindrical body 3c comprising a set of passages having all the same length but each a different internal diameter, the passages being again disposed on a circular trajectory such as to face the rotational path of the passage of the disc 2.

[0026] The lengths respectively the internal diameters of the passages or tubes of the resistance system 3 are chosen in such a manner as to define the total resistance to cerebrospinal fluid flow of the shunt system and to cover several discrete values reasonably distributed inside a range of resistance to flow of 0 - 50 mm Hg/ml/min.

[0027] Thus, by turning the disc 2, the resistance to cerebrospinal fluid flow of the valve can be adjusted to a desired value. Apparently, this adjusting process can be done after implantation and non-invasively by means of the actuator 1 which will position the disc 2 such as to allow the cerebrospinal fluid to pass through the desired passage of the resistance system 3.

[0028] The surgeon has the possibility to adjust the resistance to flow of the valve non-invasively after implantation in order to optimally fit the patient physiology, thus allowing an optimal treatment of this pathology, and in order to match the resistance of the normal resorption pathway, and therefore the average cerebrospinal fluid flow rate, according to the resorption site of a specific case. This is especially facilitated by the large range of possible values for the resistance to flow of the adjustable resistance valve, like mentioned above.

[0029] The integration of such an adjustable resistance valve into a cerebrospinal fluid shunt system is schematically shown in figure 3. As mentioned above, these devices consist of three main parts. A main body 4 of the shunt houses the adjustable resistance valve. A proximal catheter 5 to be introduced in the ventricles of the brain and allowing the draining of CSF from the ventricles is connected at one end of the main body 4. A distal catheter 6 to be introduced in a distal resorption site like the atrium, the peritoneum or the sagittal sinus and allowing drainage of CSF into this site is connected at the other end of the main body 4.

[0030] The main body 4 thus serves as a housing for the regulating means realised by the above mentioned valve, which regulates the flow of cerebrospinal fluid through the main body 4 according to the relative position of the disc 2 with respect to the resistance system 3. For this purpose, the disc 2 has to be arranged inside the main body 4 such as to allow its rotation but to exclude any fluid to pass elsewhere than through the passage formed in the disc 2, for example by using an annular joint. The resistance system 3 will be housed next to the disc 2 in such a way as to allow the fluid exiting from the passage 2a of the disc 2 to pass only through the selected passage of the resistance system 3, the cylindrical body 3c being for example in direct contact with the opposite surface of the disc 2 and the walls of the main body 4. The resistance system 3 may even be formed as a part of the main body 4, as well as the catheters 5 and 6, which are both parts well known to a person skilled in the art. Again, the previously mentioned inverse case of a fixed disc 2 and a resistance system 3 mounted such as to be rotated can be realised in a similar manner, too.

[0031] Moreover, a shunt system according to the present invention may comprise a check valve in order to avoid back flow of cerebrospinal fluid into the ventricles of the brain. These check valves being standard equipment of a shunt system, a variety of equivalent models may easily be integrated into a shunt system according to the present invention without modifying the

scope of the invention.

[0032] Finally, figure 4 schematically shows a ventriculo-sagittal implantation of a shunt system according to the present invention. The proximal end of the catheter 5 is located in the ventricles 7 of the brain 9 and crosses the cranium through a first burr hole. The distal catheter 6 is tunneled under the skin to a second burr hole that allows access to the sagittal sinus 8. The main body 4 with the adjustable resistance valve is located between the two burr holes as well as between the skin and the cranium bone.

[0033] A corresponding method of treatment of hydrocephalus using the adjustable resistance valve as described above or the corresponding cerebrospinal fluid shunt system by implanting the device into a patient's cranium and guiding the catheters to the chosen resorption sites can be performed using these informations.

[0034] An adjustable resistance valve respectively a shunt system according to the present invention is intended for use as a derivation from the ventricles of the brain to different distal resorption sites such as the sagittal sinus, the right atrium of the heart or the peritoneum. The surgeon has the possibility to adjust the resistance to flow of the valve non-invasively after implantation in order to match the resistance of the normal resorption pathway, and therefore the average cerebrospinal fluid flow rate, and in order to optimally fit the patient physiology, thus allowing an optimal treatment of hydrocephalus.

Claims

1. An adjustable resistance valve for a cerebrospinal fluid shunt system **characterised by** the fact that it comprises an actuator (1) allowing the selection of the resistance to flow of the valve, selecting means (2) with at least one passage (2a) traversing these selecting means, and a resistance system (3) comprising a set of passages defining each a different resistance to flow, the passages being situated around a circle facing said selecting means (2) such as to guide the flow of the cerebrospinal fluid traversing said passage (2a) of the selecting means (2) through the selected passage of the resistance system (3), said actuator (1) enabling to change the relative position of the selecting means (2) with respect to the resistance system (3) by a rotational movement in order to select the desired resistance of the valve.
2. Valve according to claim 1 **characterised by** the fact that the resistance system (3) comprising a set of passages corresponding to a set of resistances to flow is realised by means of a set (3a) of different tubes having each an identical internal diameter but a different length, these tubes being arranged parallel to each other, the openings being disposed

around a circle corresponding to the rotational movement of the passage (2a) of the selecting means (2).

3. Valve according to claim 1 **characterised by** the fact that the resistance system (3) comprising a set of passages corresponding to a set of resistances to flow is realised by means of a body of essentially cylindrical shape (3b) comprising a set of passages of identical internal diameter but a different length, the passages being disposed such as to form a set of passages parallel to each other and to the axis of the body (3b), with the openings of the passages facing the rotational path of the passage (2a) of the selecting means (2), the body of essentially cylindrical shape (3b) comprising on its one end a recess of helicoidal shape, on the surface of which the passages depart, in order to obtain different lengths of the passages.
4. Valve according to claim 1 **characterised by** the fact that the resistance system (3) comprising a set of passages corresponding to a set of resistances to flow is realised by means of a set of different tubes having all the same length but each a different internal diameter, these tubes being arranged parallel to each other, the openings being disposed around a circle corresponding to the rotational movement of the passage (2a) of the selecting means (2).
5. Valve according to claim 1 **characterised by** the fact that the resistance system (3) comprising a set of passages corresponding to a set of resistances to flow is realised by means of a cylindrical body (3c) comprising a set of passages having all the same length but each a different internal diameter, the passages being disposed such as to form a set of passages parallel to each other and to the axis of the body (3b), with the openings of the passages facing the rotational path of the passage (2a) of the selecting means (2).
6. Valve according to one of the preceding claims **characterised by** the fact that the lengths respectively the internal diameters of the passages or tubes are chosen in such a manner as to define the total resistance to cerebrospinal fluid flow of a corresponding shunt system and to cover a range of resistance to flow of 0 - 50 mm Hg/ml/min.
7. Valve according to one of the preceding claims **characterised by** the fact that the selecting means are realised by a disc (2) comprising at least one passage (2a) traversing the disc in a direction parallel to its longitudinal axis, the passages of the resistance system (3) preferentially being parallel to said axis.

8. Valve according to one of the preceding claims **characterised by** the fact that the actuator (1) comprises a motor connected to the selecting means (2) or to the resistance system (3) in order to drive a relative rotational movement of the selecting means (2) with respect to the resistance system (3), an energy source, and corresponding electronics that drive the motor, give feedback to the user about the actual relative position of the selecting means (2) with respect to the resistance system (3) and manage the energy consumption of the actuator (1).
9. A cerebrospinal fluid shunt system **characterised by** the fact that it comprises a proximal catheter (5) to be introduced in the ventricles of the brain and allowing the draining of cerebrospinal fluid from the ventricles, a distal catheter (6) to be introduced in a distal resorption site like the atrium, the peritoneum or the sagittal sinus and allowing drainage of cerebrospinal fluid into this site, and a main body (4) of the shunt being connected at one end to said proximal catheter (5) and at the other end to said distal catheter (6), and by the fact that the main body (4) houses an adjustable resistance valve comprising an actuator (1) allowing the selection of the resistance to flow of the valve, selecting means (2) with at least one passage (2a) traversing these selecting means, and a resistance system (3) comprising a set of passages defining each a different resistance to flow, the passages being situated around a circle facing said selecting means (2) such as to allow the flow of the cerebrospinal fluid traversing said passage (2a) of the selecting means (2) through the selected passage of the resistance system (3), said actuator (1) enabling to change the relative position of the selecting means (2) with respect to the resistance system (3) by a rotational movement in order to select the desired resistance of the valve.
10. A cerebrospinal fluid shunt system according to claim 9 **characterised by** the fact that the main body (4) serves as a housing for said valve, which regulates the flow of cerebrospinal fluid through the main body (4) according to the relative position of the selecting means (2) with respect to the resistance system (3), these selecting means (2) or this resistance system (3) being arranged inside the main body (4) such as to allow its rotation but to exclude any fluid to pass elsewhere than through the passage (2a) formed in the selecting means (2) and the selected passage of the resistance system (3).
11. A cerebrospinal fluid shunt system according to one of the claims 9 or 10 **characterised by** the fact that it comprises a check valve avoiding back flow of cerebrospinal fluid into the ventricles of the brain.
12. A method of treatment of hydrocephalus **characterised by** the fact that a cerebrospinal fluid shunt system is implanted into a patients cranium and that the catheters are guided to the chosen resorption sites, the cerebrospinal fluid shunt system comprising a proximal catheter (5) to be introduced in the ventricles of the brain and allowing the draining of cerebrospinal fluid from the ventricles, a distal catheter (6) to be introduced in a distal resorption site like the atrium, the peritoneum or the sagittal sinus and allowing drainage of cerebrospinal fluid into this site, and a main body (4) of the shunt being connected at one end to said proximal catheter (5) and at the other end to said distal catheter (6), said main body (4) housing an adjustable resistance valve comprising an actuator (1) allowing the selection of the resistance to flow of the valve, selecting means (2) with at least one passage (2a) traversing these selecting means, and a resistance system (3) comprising a set of passages defining each a different resistance to flow, the passages being situated around a circle facing said selecting means (2) such as to allow the flow of the cerebrospinal fluid traversing said passage (2a) of the selecting means (2) through the selected passage of the resistance system (3), said actuator (1) enabling to change the relative position of the selecting means (2) with respect to the resistance system (3) by a rotational movement in order to select the desired resistance of the valve.

Fig.1a

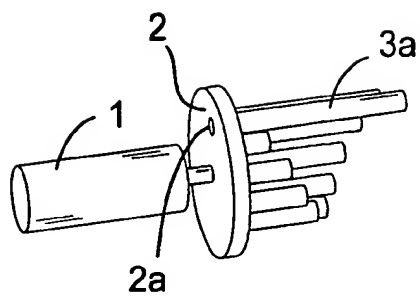


Fig.1b

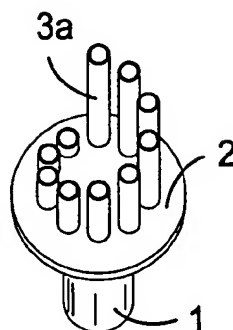


Fig.1c

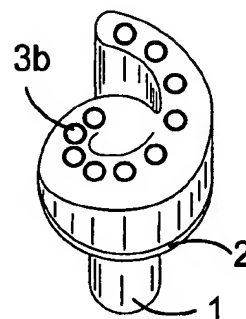


Fig.2a

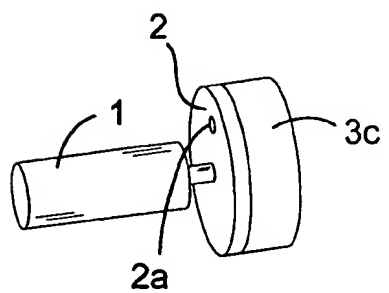


Fig.2b

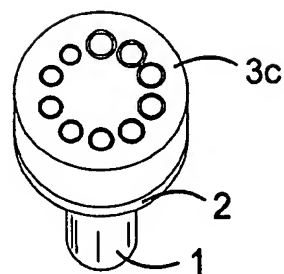


Fig.3

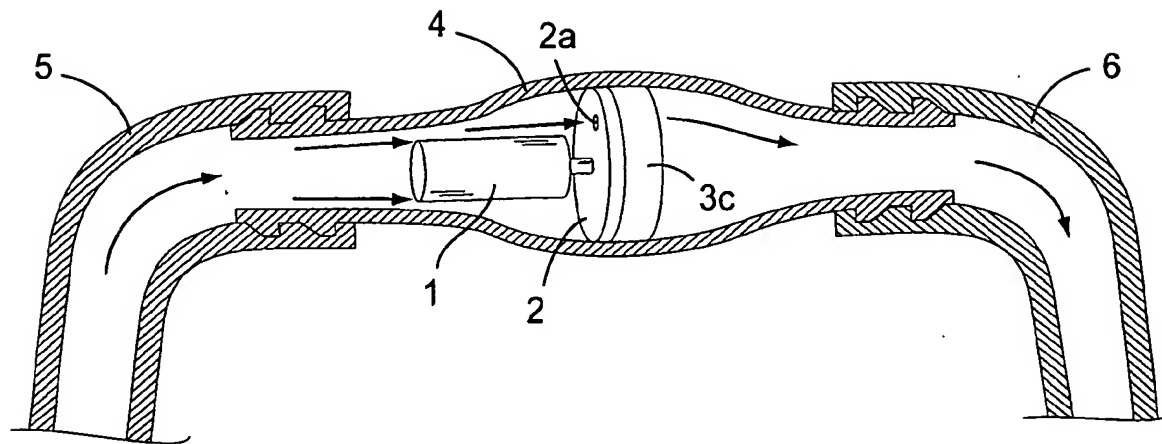
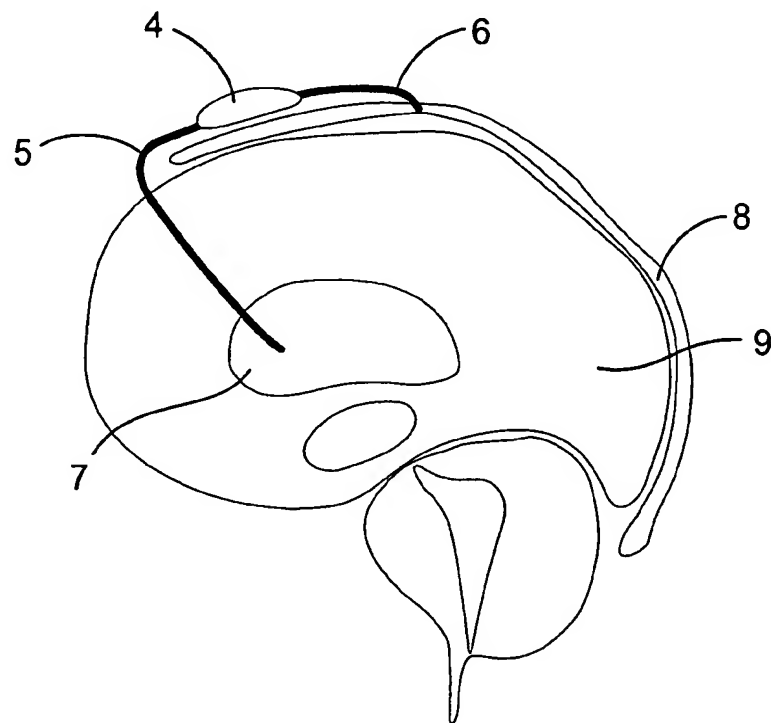


Fig.4





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INCOMPLETE SEARCH
SHEET C

Application Number
EP 02 01 7363

Claim(s) searched completely:
1-5,7-11

Claim(s) not searched:
12

Reason for the limitation of the search (non-patentable invention(s)):

Claim 12 - Method for treatment of the human or animal body by surgery or therapy (Art. 52(4) EPC).

Further limitation of the search

Claim(s) searched completely:
1-5,7-11

Claim(s) not searched:
6

Reason for the limitation of the search:

Claim 6 - the claim attempts to define the subject-matter by a result to be achieved instead of clearly defining all the technical features which are essential to obtain the desired technical effect. Too many undetermined parameters (materials used, surface properties, fluid properties, temperature, pressure ...) put an undue burden to the skilled person to determine the scope of protection sought for, and render a complete search impossible.

European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 02 01 7363

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
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			TECHNICAL FIELDS SEARCHED (Int.Cl.7)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 01 7363

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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